UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

LAKE CHARLES DIVISION

TINA JOHNSON	:	**DOCKET NO. 2:10 CV 404**
VS.	:	**JUDGE MINALDI**
TEVA PHARMACEUTICALS USA, INC.; QUALITEST; WYETH, INC. d/b/a WYETH; SCHWARZ PHARMA, INC.; ALAVEN PHARMACEUTICALS, LLC.	:	**MAGISTRATE JUDGE KAY**

MEMORANDUM RULING

Before the Court is a Motion to Dismiss filed by defendants Wyeth, LLC[1] and Schwarz Pharma, Inc. [doc. 13]. Also before the Court is a Motion to Dismiss filed by defendant Alaven Pharmaceuticals, LLC (defendants hereinafter referred to collectively as "Wyeth") [doc. 19]. Alaven's motion incorporates all arguments in the original motion. The plaintiff, Tina Johnson ("Johnson"), filed an Opposition to both motions. [doc. 21]. Wyeth filed a Reply [doc. 28].

FACTS

Metoclopramide is a prescription drug approved by the FDA to treat gastroesophageal reflux disease. Metoclopramide is available in both brand (Reglan) and generic formulation. Since the mid-1980s, several companies, including defendants Teva Pharmaceuticals USA, Inc. ("Teva") and Qualitest, have manufactured and distributed generic metoclopramide. From approximately 1989

[1] Johnson named Wyeth LLC in the Complaint as Wyeth, Inc. *See* Complaint [doc. 1].

until February 2008, Wyeth manufactured and distributed Reglan tablets.[2]

On March 12, 2010, Johnson filed suit against Wyeth and other defendants, alleging that she suffered injuries after ingesting generic metoclopramide tablets from July 2002 through and until March 2009.[3] Johnson avers that as a result of ingesting these tablets, she developed the neurological condition tardive dyskinesia.[4]

Johnson's complaint asserts a claim under the Louisiana Products Liability Act ("LPLA") against defendants Teva and Qualitest.[5] Johnson asserts three claims against Wyeth in its capacity as former brand name manufacturers of Reglan: (1) under the Louisiana Unfair Trade Practices and Consumer Protection Law ("LUTPA"); (2) for breach of express and implied warranties; and (3) for misrepresentation and fraud.[6]

RULE 12(b)(6) STANDARD

A motion filed pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure challenges the sufficiency of a plaintiff's allegations. Fed. R. Civ. P. 12(b)(6). When ruling on a 12(b)(6) motion, the court accepts the plaintiff's factual allegations as true, and construes all reasonable inferences in a light most favorable to the plaintiff or nonmoving party. *Gogreve v. Downtown*

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[2] Wyeth, LLC manufactured and distributed Reglan tablets from 1989 until late December 2001. In late December 2001, Schwarz Pharma, Inc. acquired the rights to Reglan tablets from Wyeth, LLC and thereafter manufactured and sold Reglan tablets until February 2008. In February 2008, Schwarz transferred its rights to Reglan tablets to Alaven. Complaint [doc. 1].

[3] Complaint [doc. 1].

[4] *Id.*

[5] *Id.*

[6] *Id.*

Develop. Dist., 426 F. Supp.2d 383, 388 (E.D. La. 2006).

To avoid dismissal under a Rule 12(b)(6) motion, a plaintiff must plead enough facts to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1974 (2007). "Factual allegations must be enough to raise a right to relief above the speculative level...on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 1965. Accordingly, a plaintiff must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.*

ANALYSIS

Wyeth seeks dismissal of Johnson's claims, arguing that Wyeth cannot be held liable under Louisiana law for injuries caused by another manufacturer's product. Wyeth contends that the LPLA is the exclusive remedy for products liability claims in Louisiana and notes that the LPLA authorizes only four theories of recovery: (1) construction or composition defect; (2) design defect; (3) inadequate warning; or (4) breach of express warranty. Wyeth argues that Johnson's claims - unfair trade practices, breach of implied and express warranty, and misrepresentation and fraud - must fail because Johnson's claims fall outside the scope of the LPLA. Wyeth adds that even if Johnson had properly asserted these claims under the LPLA, such claims would fail to meet the required elements of an LPLA action because Johnson cannot establish that Wyeth is a manufacturer of the product. Wyeth points to Johnson's allegations that Teva and Qualitest manufacture the product that allegedly injured her.

Wyeth notes that Louisiana state and federal courts have recognized that Wyeth does not have a duty to warn about another manufacturer's drug and points to at least six rulings in which

Louisiana courts have rejected the theory that manufacturers of brand name drugs owe a legal duty to consumers of a generic equivalent of the drug.[7] Wyeth adds that Louisiana law is consistent with decisions from other jurisdiction that have also rejected the theory that brand name drug manufacturers are liable for injuries caused by generic products.[8]

Finally, Wyeth argues that Food and Drug Administration ("FDA") regulations do not impose a duty on brand name manufacturers. Wyeth notes that none of the statutes or regulations referenced by Johnson impsoses a duty or otherwise suggests that the brand name manufacturer is responsible for the label of its competitors' generic drugs. Rather, Wyeth argues that the regulations cited by Johnson establish the labeling requirements for all prescription drugs. Wyeth insists that these regulations merely confirm that brand name manufacturers are responsible for their drugs and labels and nothing more.

Johnson contends that Wyeth, as the Reference Listed Drug ("RLD") holder, had a continuing responsibility to provide accurate labeling. Johnson notes that FDA regulations provide that the RLD labeling shall be "revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug."[9] Johnson notes that Wyeth did not take any action to change the contents of its label once it was aware of the association of serious hazards with metoclopramide; thus, Johnson argues that Wyeth breached its duty to provide an accurate warning.

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[7] *See, e.g. Stanley v. Wyeth*, 2007-2080 (La. App. 1 Cir. 5/2/08); 991 So. 2d 31; *Washington v. Wyeth*, 2010 WL 450351 (W.D. 2010); *Morris v. Wyeth*, 2009 WL 4061403 (W.D. La. 2009).

[8] *See* Def.'s Memo. in Support of MTD, pp. 9-11 [doc. 13-1].

[9] *See* 21 C.F.R. § 201.57(e); *see also* 21 C.F.R. § 314.70(C)(6)(iii)(c) (promulgating procedure to "add or strengthen" warning to increase safe use of the drug).

Johnson argues that Wyeth may also be liable under Louisiana law for its failure to provide adequate and accurate warnings. Johnson notes that Louisiana courts follow the foreseeability standard and argues that Wyeth reasonably must have foreseen that its inadequate warnings would have been relied upon by makes, users, and prescribers of the generic form of Reglan. Johnson contends that the LPLA establishes the exclusive theories of liability for manufacturers for damage caused by their products. Johnson acknowledges that she has not alleged that Wyeth manufactured or sold the product that caused her alleged injuries; thus, Johnson argues that the LPLA is inapplicable to her claims against Wyeth. Instead, Johnson argues that she has stated viable claims against Wyeth for negligent misrepresentation, fraudulent misrepresentation, a cause of action under LUTPA, and breach of implied warranty.

The LPLA authorizes four theories of recovery: (1) construction or composition defect; (2) design defect; (3) inadequate warning; or (4) breach of express warranty. La. Rev. Stat. Ann. § 9:2800.52-54. A plaintiff may not recover from a manufacturer for damage caused by a product on the basis of any theory not set forth in the LPLA. *Jefferson v. Lead Industries, Ass'n., Inc.*, 106 F.3d 1245, 1250-51 (5th Cir. 1997).

Louisiana courts have consistently held that brand name manufacturers are not responsible for warning consumers about another manufacturer's drugs. For example, the Louisiana First Circuit Court of Appeal has held that "a name brand drug manufacturer owes no legal duty to the consumer of a generic equivalent of its drug." *Stanley v. Wyeth*, 991 So. 2d at 32. In *Stanley,* the plaintiffs conceded that Wyeth did not manufacture the drug ingested by the plaintiffs, but attempted to assert claims against Wyeth in "a negligent misrepresentation action and not an action under the LPLA." *Id.* at 33. The court disagreed and held that a manufacturer "cannot reasonably expect that

consumers will rely on information they provide when actually ingesting another company's drug." *Id.* at 34 (quoting *Foster v. American Home Prods. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994)).

Federal courts in this district have come to similar conclusions regarding a brand name drug manufacturer's duty to warn consumers of its generic equivalent drug. In two related cases, plaintiffs brought negligent misrepresentation claims outside the scope of the LPLA. Both courts rejected the plaintiff's contention that the company had a duty to warn of the product's dangers, even though it did not manufacture the product. *Tarver v. Wyeth*, 2005 WL 4052382 (W.D.La 2005); *Tarver v. Wyeth*, 2006 WL 1517546 (W.D. La. 2006). The Court explained, "the law is clear that Louisiana imposes on a manufacturer no duty to warn of the dangers of another company's product." *Tarver v. Wyeth*, 2005 WL 4052382 at *2. In another case, the same federal court has explained that "[t]he Louisiana Legislature has chosen to make the LPLA the exclusive source of liability to be used against manufacturers for damages caused by their products and the warnings associated with those products." *Morris v. Wyeth*, 2009 WL 4061403 at *4.

The LPLA establishes the exclusive theory of liability that may be asserted against manufacturers for injuries caused by their products. Johnson has not alleged that Wyeth manufactured the generic drug that allegedly caused her injuries, nor has Johnson alleged any claims against Wyeth under the LPLA. Moreover, Louisiana state and federal courts have made it clear that brand name drug manufacturers do not owe a continuing duty to consumers of the generic drug equivalent. As Louisiana law prohibits Johnson from asserting her claims as independent causes of action, each claim fails to state a claim for relief. Accordingly,

IT IS ORDERED that the Motions to Dismiss, [docs. 13, 19] are hereby GRANTED. All

of the plaintiffs' claims against Wyeth, Schwarz, and Alaven are hereby DISMISSED with prejudice at the plaintiff's cost.

Lake Charles, Louisiana, this 11 day of August, 2010.

PATRICIA MINALDI
UNITED STATES DISTRICT JUDGE